

RESEARCH ARTICLE

Buprenorphine Outpatient Outcomes Project: can Suboxone be a viable outpatient option for heroin addiction?

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Background: Opioid dependence treatment traditionally involves methadone clinics, for which dispensing schedules can be cumbersome. Buprenorphine, a partial agonist of the mu receptor and antagonist of the kappa receptor, is a potential outpatient alternative to methadone. Funded by a grant from the State of Maryland's Community Health Resources Commission (CHRC), the Buprenorphine Outpatient Outcomes Project (BOOP) evaluates the outcome of Suboxone (buprenorphine/naloxone) treatment on abstinence from heroin use, rates of emergency room visits and hospitalizations, legal issues, and quality of life.

Methods: Active heroin users were recruited between June 2007 and June 2010 and induction therapy with Suboxone was instituted during hospitalization. Once discharged, patients were followed as outpatients for maintenance treatment and counseling. Data were collected from electronic medical records, Maryland state legal records, and SF-36® Health Surveys regarding several parameters and patients were categorized according to duration of treatment with Suboxone into one of three groups: <1 month, 1–3 months, and >3 months.

Results: A total of 220 participants were included in the study. The age range of participants was 18–67 years with most being African American males. Eighty-three (38%) remained in the study for at least 1 month, with 37 of the 83 (45%) remaining in treatment for >3 months. Ten of the 37 (27%) never relapsed after their longest period of abstinence from heroin. During the first year after initiating treatment with Suboxone, hospitalization and emergency room visit rates for all 220 participants decreased by 45 and 23%, respectively, as compared to the year prior to starting treatment. The number of legal charges for drug possession decreased from 70 to 62. Anecdotally, the quality of life seemed to improve in those who were treated with Suboxone for longer periods of time and received regular counseling.

Conclusion: Overall, Suboxone is an effective treatment method for heroin addiction and is a viable outpatient therapy option. Individualized treatment plans and counseling must be implemented for maximum benefits to be seen. Retention of patients for a long duration of therapy was difficult, but for those who did remain, benefits were seen in overall health, abstinence from heroin use, cognition, and quality of life.

Keywords: Suboxone; heroin abuse; substance abuse treatment; quality of life

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The National Survey on Drug Use and Health noted that in 2011, 426,000 people were dependent on heroin (1); however, only a small fraction was receiving treatment. Treatment, defined as hospital inpatient, rehabilitation, or mental health centers, has been an issue with regards to access for all interested as in 2011; 21.6 million people in the United States needed treatment; however, only 2.3 million were able to attain that. In Baltimore City alone, between 1999 and 2003, heroin use increased from 12,040 self-reported cases of use to 17,309 cases (2).

Methadone, a full opioid agonist, has commonly been used to treat heroin addiction and can be cumbersome for many patients due to the frequent dispensing schedules imposed by many treatment centers. Suboxone (buprenorphine/naloxone), a partial agonist, can be used as an outpatient method of treatment and therefore may be more desirable for patients battling heroin addiction.

The Buprenorphine Outpatient Outcomes Project (BOOP), funded by the State of Maryland's Community Health Resources Commission, was a study aimed at exploring the impact of inpatient to outpatient treatment

with Suboxone on abstinence from heroin use, rates of emergency room visits and hospitalizations, legal issues, and quality of life.

Methods

IRB approval was sought and obtained prior to commencing the study. Patients actively using heroin were recruited between June 2007 and June 2010 and identified as candidates through clinical history, urine toxicology results, and pharmacy orders. Informed consent was obtained and induction therapy with Suboxone was instituted during hospitalization (during withdrawal period from heroin).

Once discharged, patients were followed as outpatients for maintenance treatment and counseling. Patients were seen on a weekly basis for the first month, bi-weekly during the second month, and every month thereafter. If the patient relapsed, they would resume weekly visits for 2 weeks, bi-weekly for a month, and then resume once-monthly visits thereafter. Mandatory counseling was provided on a weekly basis for the first month and every 2 weeks in the second month. Patients were then counseled once every month thereafter at the patient's discretion.

At every patient encounter, patients were seen by a resident physician and an attending physician to discuss how the patient was doing on their current dose of Suboxone and to adjust the dosage as needed. Data were collected from electronic medical records, Maryland state legal records, counseling records, and *SF-36® Health Surveys* regarding demographics, epidemiological and clinical parameters, criminal charges, and quality of life measures. Patients were categorized according to duration of treatment with Suboxone into one of three groups: <1 month, 1–3 months, and > 3 months. Patients were followed until June of 2011.

Results

Over a 4-year period, 220 participants were successfully recruited and treated with Suboxone for heroin addiction. All points of analyses were undertaken and analyzed for one community hospital only. Demographic data of the 220 participants are presented in Table 1. Of note, most participants were male, under the age of 50, unemployed, and African American. While most participants were only in the study for less than 1 month (137, 62%), 46 (21%) remained for 1–3 months, and 37 (17%) participated for more than 3 months.

Hospitalizations and emergency room data were examined for each of the three participant groups and are presented in Fig. 1. In those who stayed in the program for less than 1 month, there were 237 hospitalizations and 370 emergency room visits of these patients in the year prior to starting treatment with Suboxone. Of those that stayed in the program more than 3 months, there were 56 noted hospitalizations and 84 emergency

Table 1. Demographics of the recruited participants

Mean age, years	46
Age range, years	18–67
<50 years old, %	72
50 years and older, %	28
Male, %	63
Female, %	37
African American, %	85
Caucasian, %	15
Unemployed at consent, %	79
Employed at consent, %	8

room visits. However, in the year after being started on Suboxone therapy, even if it was not continued long term, there was a noted decrease in the number of hospitalizations and emergency room visits at our hospital. Nineteen of the 37 people (51%), who remained in treatment for more than 3 months, never had a hospitalization at our hospital after starting treatment.

The number of legal charges was also examined 1 year prior to starting treatment as compared to 1 year after initiating treatment. It was noted that although cumulatively the number of charges increased from the year prior to starting treatment to the year after, the number of some individual types of charges dropped. Most noticeably, the number of charges for illicit drug possession decreased from 70 charges in the year prior to 62 charges in the year after starting treatment. Other types of charges that also decreased in number were prostitution, fraud, violation of probation, and trespassing. Table 2 shows the breakdown of the number of charges in each of the treatment groups.

Quality of life, as perceived by the patient, was measured using the SF-36 Version 2 Questionnaire. Specific questions tailored to evaluate the patient's own perception of each of the eight individual and two overall parameters were completed at specific intervals during treatment to monitor the patient's-perceived progress while being treated for heroin addiction with Suboxone. The overall physical health and overall mental health are an amalgamation of each of the eight health parameters. Table 3 explains the descriptions of each of the individual parameters.

Figure 2 shows the overall trend of each of the eight individual health parameters and the patient perception of overall mental and physical health. It is seen that over a 12-month period, those who completed SF-36 questionnaires at each of the monthly intervals showed a progressive improvement proportional to the length of treatment with Suboxone. When comparing the scores at baseline (0 months) to the scores at 12 months into treatment, an overall increase in patient-perceived mental, physical, and emotional health can be seen.

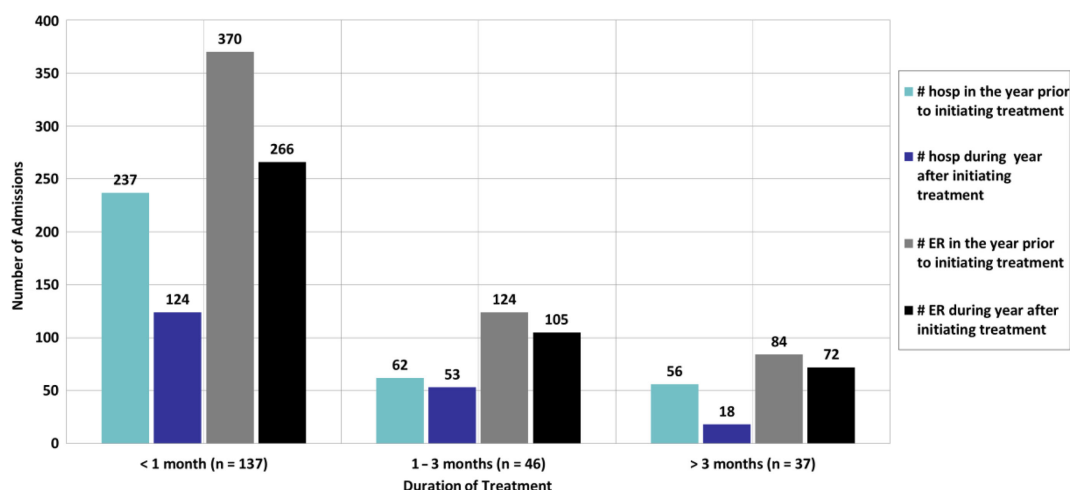


Fig. 1. Number of emergency room visits and hospitalizations 1 year prior to starting treatment compared to 1 year after.

Discussion

Suboxone is a viable treatment option for heroin addiction in a closely monitored inpatient-to-outpatient setting and, more importantly, can be part of a standard outpatient doctor-patient relationship. Advantages of using Suboxone have been studied in the past and include lower dependence, less tolerance, milder withdrawal symptoms, lower risk of fatal overdosing, and longer lasting action (4–6). Though Suboxone has been marketed as an office-based treatment option for prescription opioid abuse, we found that using this drug for heroin abuse does have potential as an alternative to the cumbersome and federally mandated option of methadone. Though long-term patient retention was noted to be a problem in our study

(likely due to other substance abuse issues such as alcohol or cocaine or severe mental health issues such as psychosis or manic/depressive disorders), it was seen that there was an overall decrease in return hospital and ED visits at Medstar Union Memorial Hospital and an improvement in patient perception of quality of life.

Per the Drug Abuse Warning Network (DAWN) publication, National Estimates of Drug-Related Emergency Department Visits, in 2011 it is estimated that approximately 5 million ED visits nationwide were for illicit drug-related issues, with 2.5 million being due to drug misuse or abuse (7). Illicit drug use with heroin alone was associated with 20.6% of these ED visits and demographically these patients were noted to be male, between the ages of 21–29 and 35–44, and Caucasian race (7). In our community hospital study, we noted that there also was a high number of ED visits and hospitalizations associated with drug abuse which declined in the year after starting treatment with Suboxone, likely attributed to the fact that patients now had ongoing medical care in an outpatient setting along with heroin addiction treatment, that would likely prevent the need to seek other sources of help.

In 1997, the number of federal prisoners who admitted to using drugs prior to committing a crime was 44.8%; by 2004, that number had risen to 50.2% (8). Eighteen percent of prisoners reported procuring drug money as their motive (2). While there have been studies looking at the success of methadone programs in reducing crime rates post-intervention, research evaluating Suboxone treatment and its effect on crime rate is lacking. Baltimore has high levels of drug addiction, with an estimated 40,000 heroin addicted residents, or approximately 6% of the population (9). In our study, it was noted that although the total number of legal charges did increase over the course of 1 year after starting treatment, certain individual types of legal charges had actually decreased,

Table 2. Number of legal charges: 1 year prior and 1 year post starting treatment with Suboxone

Duration of treatment	Number of charges: 1 year prior to starting treatment	Number of charges: 1 year post starting treatment
< 1 month (n = 137)	156 (n = 55 people)	170 (n = 56 people)
1–3 months (n = 46)	44 (n = 17 people)	43 (n = 18 people)
> 3 months (n = 37)	21 (n = 11 people)	24 (n = 10 people)
Total	221 charges*	237 charges*

*Though cumulatively the number of charges increased from the year prior to starting treatment to the year after, the number of some individual types of charges dropped. Most noticeably, the number of charges for illicit drug possession decreased from 70 charges in the year prior to 62 charges in the year after starting treatment. Other types of charges that also decreased in number were prostitution, fraud, violation of probation, and trespassing.

Table 3. Definition of each individual category of measured SF-36 questionnaire variables

Parameter	Description
Physical functioning	Ability to perform physical activities (i.e., bathing, dressing, etc.)
Role – physical	Ability to carry out work functions or other daily activities physically
Bodily pain	Amount of pain experienced on daily basis and limitations as a result
General health	Patient's own perception of personal health
Vitality	Patient's perception of amount of energy
Social functioning	Ability to have normal social interactions without interference due to physical or emotional problems
Role emotional	Ability to carry out work functions or other daily activities without emotional/mental interference
Mental health	Patient's perception of emotional state (i.e., depressed/nervous vs. calm/happy)

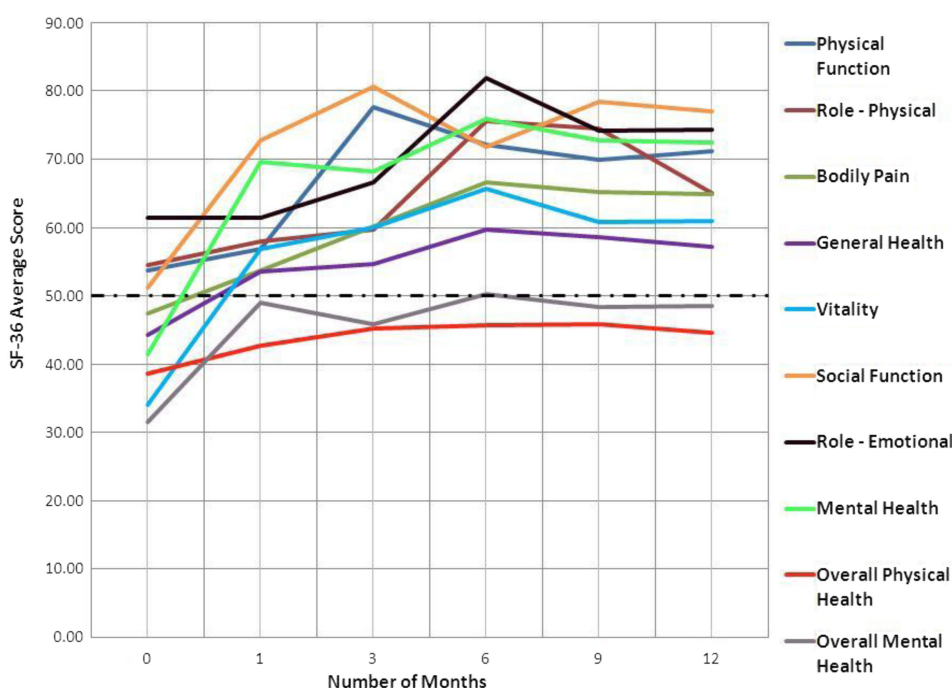
As adapted from the SF-36 version user manual (3).

such as illicit drug possession, prostitution, fraud, violation of probation, and trespassing. Anecdotal personal statements from patients noted that they felt less need to commit crimes to support their habits once they started treatment.

Quality of life was also assessed during our study where patients completed questionnaires at regular intervals during treatment to assess their own response to how they were progressing with treatment with respect to mental and physical health modalities. Overall, an improvement was noted in those who completed at least 12 months of treatment; however, treatment must be individualized to allow for best outcomes as each patient is different in their comorbidities and substance abuse habits. We believe that counseling should be made a

mandatory part of drug abuse treatment. Our data show that while there was some noted improvement in quality of life over a 12-month period, it emphasizes the point that Suboxone treatment is not something that can be generalized to all patients, but rather individualized, taking into account the patient's mental and physical health at interval points during treatment.

Due to the less stringent dosing schedules available when using Suboxone, each patient must be initially assessed and have their treatment plan tailored individually to allow for the best possible retention rate in treatment and overall health and abstinence outcomes. As per Hser et al. (10), factors influencing retention have not been well studied but this study along with a meta-analysis done in 2012 based on 21 randomized clinical trials

**Fig. 2.** Average SF-36 scores of the patients who were treated for at least 12 months ($n = 12$).

indicated that a higher dose of buprenorphine (16–32 mg) predicted better retention and that positive urine toxicologies predicted dropout and likely return to opiate abuse, especially those positive for cocaine (11).

Counseling must be made a mandatory part of treatment with Suboxone, as this allows for treatment of the mental and emotional aspects of heroin addiction. It may also improve adherence to treatment especially in the first month, which in our study, showed a 62% dropout rate. While we did not recruit those with severe mental health issues as we did not have the capabilities to adequately treat these disorders in addition to the heroin addiction, these are equally as important to address as the physical manifestations of heroin abuse, as these aspects can derail patients from seeking further help for their addiction or preclude them from maintaining abstinence from further use.

By providing regular outpatient follow-up, Suboxone at no cost to the patient, and working with the patient to attain medical insurance for those who did not have any, we believe this allowed for better medical follow-up and less need to seek treatment through emergency departments/hospitalizations. For providers, becoming licensed is a simple 8-hour process to receive a federally approved waiver. This will ultimately increase access to treatment for patients and would most benefit those who are serious about abstinence from heroin and do not have compliance issues. Though Suboxone is becoming a more widely used option, surveys conducted amongst physicians noted that complexity of induction, medication costs, and regulatory limits have posed barriers to prescribing (12). Therefore, more education/research and funding are required to improve access to the medication and all its benefits. Additionally, medical insurance as a mandatory part of healthcare in general is needed to help with the high costs of Suboxone therapy and frequent outpatient visits.

Limitations of our study include that our study population was only monitored in our facility due to small staff size and financial resources that only allowed us to garner our data and patient population from one community hospital. Therefore, it is unknown if help was sought at other outside institutions and their outcomes. Also, we did not have a control group that was not being treated with Suboxone to compare outcomes of the parameters previously discussed. This is something that could be further investigated in a larger population and hospital setting where resources to do so would be more abundant.

Another limitation includes the lack of statistical evaluation of our data. We merely wanted to bring attention to this treatment modality and show in overall numbers our individual successes with using Suboxone as a treatment modality for heroin abuse. As our study was funded by a generous grant from the State of Maryland, it was

not enough to undertake all that could be done in terms of comparison groups and detailed analyses. In future, joining forces with other institutions and outpatient programs could provide valuable information to further build on what we have attempted to bring to light in this paper.

We were also not able to determine costs incurred by hospitalizations or ED visits as compared to outpatient treatment visit costs and medication costs (though provided free to our patient population) to assess whether there is a cost-benefit to undertaking such treatment. Also, the number of participants per length of treatment group decreased from baseline, with most dropping out due to relapse or concurrent cocaine use that prevented them from adhering to the stringent rules of the program, Suboxone administration and therapy schedules, therefore the groups were not matched in terms of number of participants. And lastly, legal charges were only surveyed in the state of Maryland and therefore we were unable to determine if any legal issues occurred outside of the state.

In conclusion, benefits in health, abstinence from heroin use, cognition, and quality of life were seen in those who remained in the program for at least 12 months. Physicians prescribing Suboxone in an outpatient setting must have the necessary adjuncts to medical treatment, such as counseling/social work services and pharmaceutical/lab/medical staff, as these patients usually have many clinical and social challenges that need to be addressed. Most patients have intercurrent illnesses such as hepatitis or HIV, other addictions such as alcohol and/or cocaine abuse, or mental health issues that can all affect the course of treatment for heroin addiction. Due to these factors, length of treatment and dosing schedules for Suboxone need to be individually tailored to the patient and therefore it is difficult to ascertain a general guideline with respect to these factors.

In order to have the best possible outcome for abstinence from heroin, all issues must be addressed in one setting. It is necessary to have multidisciplinary staff and resources available in the outpatient setting to have a seamless inpatient-to-outpatient transition and retention in treatment. By decreasing the stigma of treating heroin addiction in an outpatient setting and making physicians aware and educated about Suboxone and the certification guidelines set by the Drug Addiction Treatment Act of 2000 (DATA 2000), we may be able to increase access for such addicted patients who are seeking help, decrease ED visits/hospitalizations, legal issues, and improve the patient's overall quality of life.

Conflict of interest and funding

The authors have no conflict of interest. Funding was provided by a generous grant from the State of Maryland's Department of Health and Mental Hygiene.

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